

REMARKS

I. INTRODUCTION

Claims 142-146 were indicated as being allowed. Applicants appreciate the Examiner's participation in an interview with Applicants' attorney and Dr. Guillermo J. Tearney (one of the inventors) on January 31, 2011 (the "Interview"), and the Examiner's suggestion that the subject matter of claims 69, 73 and 75 be included in other independent claims. (See Interview Summary dated February 22, 2011).

Claims 69, 73, 75, 95, 152, 155 and 158 have been cancelled above, without prejudice. Claims 68, 74, 76, 81, 82, 84, 89, 96-98, 101, 102, 113-115, 121, 125-127, 131-133 and 142-146, but not for any reasons relating to patentability thereof. Indeed, independent claims 68, 89, 113, 125 and 131 have been amended to incorporate the subject matter of now cancelled claims 69, 73 and 75, as suggested by the Examiner during the Interview. Dependent claims 74, 76, 81, 82, 84, 96-98, 101, 102, 114, 115, 121, 126, 127 and 131-133 have been amended to remove minor informalities therefrom, remove a dependency from a cancelled claims, and correspond the recitations provided therein to the amendments made in the amended independent claims from which they depend, as applicable.

Indeed, during the Interview, the Examiner agreed that the subject matter of now-cancelled claims 69, 73 and 75 has already been searched during the prosecution of the present application. Thus, the Examiner indicated that the entry of the amendments to independent claims 68, 89, 113, 125 and 131 to include such subject matter of cancelled claims 69, 73 and 75 would be permitted and entered, as not introducing the subject matter which has not been searched.

Accordingly, claims 68, 70-72, 74, 76-82, 84-94, 96-102, 104-148, 150, 151, 153, 154, 156, 157 and 159-162 are still under consideration in the above-referenced application. Provided above, please find a claim listing indicating the amendments to claims 68, 74, 76, 81, 82, 84, 89, 96-98, 101, 102, 113-115, 121, 125-127, 131-133 and 142-146, the cancellation of claims 69, 73, 75, 95, 152, 155 and 158, and the status of other claims on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

II. IMPROPRIETY OF OFFICE ACTION DESIGNATION

During the Interview, Applicants presented argument as to the impropriety of the designation of the present Office Action as being “final”. Applicants’ attorney thanks Examiner Kish for the courtesies extended by the Examiner at the interview. During the Interview, Applicants’ represented confirmed that the amendments to the claims contained in the prior Amendment and Response to the Final Office Action filed with the Request for Continued Examination (dated December 8, 2010) could not have been presented previously, and including additional subject matter which was argued separately in such prior Amendment and Response. To that end, the amended recitations of one or more the claims were not directed to the same invention (contrary to the Examiner’s contentions provided in the latest Final Office Action), and not presented prior to the amendments made in such prior Amendment and Response.

Thus, Applicants respectfully assert that the additional arguments presented by the Examiner in the latest Final Office Action were necessitated by the amendments to the claims made in December 28, 2010 Amendment, and therefore the finality of the

rejections contained in the latest Office Action is improper pursuant to M.P.E.P. 706.07(b). Accordingly, a withdrawal of the finality of the present Office Action is respectfully requested.

III. OBJECTIONS TO CLAIMS 142-146 SHOULD BE WITHDRAWN

Claims 142-146 stand objected to as because of minor informalities. In particular, the Examiner believes the discussion of the number of resolvable points to be as low as 100 is unclear. (See Final Office Action, p. 4). In the Final Office Action, the Examiner admits that the number of resolvable points can be as low as 625. (See *id.*) As the Examiner shall ascertain, claims 142-146 have been amended above to recite that there are at least 625 spectrally-resolvable points. Accordingly, the objection to claims 142-146 is now moot, and should therefore be withdrawn.

IV. REJECTIONS UNDER 35 U.S.C. §§ 102(b) AND 103(a) SHOULD BE WITHDRAWN

Claims 68-75, 81, 82, 84-87, 89-95, 101, 102, 104-107, 109-116, 118-128, 130, 137-140, 147-157, 161 and 162 stand finally rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 5,318,024 issued to Kittrell et al. (the “Kittrell Patent”). Claims 88, 108, 117, 129, 131-136, 141 and 158-160 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Kittrell Patent, in view of U.S. Patent No. 3,941,121 issued to Olinger et al. (the “Olinger Patent”). Claims 76-78 and 96-98 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Kittrell Patent, in view of International Publication No. WO 99/44089 by Webb et al. (the “Webb Publication”). Claims 79, 80, 99 and 100 stand finally rejected under 35 U.S.C.

§103(a) as allegedly being unpatentable over the Kittrell Patent, in view of U.S. Patent No. 5,275,594 issued to Baker et al. (the “Baker Patent”). Applicants respectfully assert that the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent, fails to teach, suggest or disclose the subject matter recited in amended independent claims 68, 89, 113, 125 and 131 (which include the subject matter of now-cancelled claims 69, 73 and 75), and the claims which depend therefrom, for at least the following reasons.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; *also see Lindeman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

Under 35 U.S.C. § 103(a), a person is not entitled to a patent even though the invention is not identically disclosed or described as set forth in §102, “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of

ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the “TSM test”). See *In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit’s application of the TSM test, see *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; see *In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007). Further, the Court underscored that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, “the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure.” *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in applicant's disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. See *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

The Kittrell Patent describes a laser endoscope for generating a spectrally resolved spatial image of tissue. Fiber optics positioned within an optically shielded endoscope are used to deliver laser radiation to tissue to be imaged. Radiation returning through the fiber optics from the tissue is spectrally resolved and used to generate an image of tissue that can assist in diagnosis and treatment. (See Kittrell Patent, Abstract).

A generalized spectral system is shown in Figs. 21 and 22 of the Kittrell Patent. As illustrated in Fig. 21, an excitation light 95 is sent from a laser or conventional light source into a selected optical fiber 20. This light passes through a beam splitter 52 or a mirror with a hole 50 (as shown in Fig. 22), and focused onto the input end 40 by a lens 41. The light exits the distal end of the optical fiber 20, passes through the optical shield 12,

and impinges on the tissue 34 (of Fig. 4). The fluorescence and scattered light is returned via the same or a different optical fiber 20 to the proximal end 40 of the optical fiber 20. This return light 54 is separated by the beam splitter 52 or by the mirror 50 with hole 51 (see Fig. 22), and enters a spectrum analyzer 60. A diffraction grating 68 of the spectral detector 65 can disperse the return light from a target. The dispersed light is projected onto a multichannel detector 70 which has many detectors. (See *id.*, col. 19, lns. 20-47). Fig. 13B of the Kittrell Patent illustrates the use of a prism, but without any lens.

The Olinger Patent relates to a needle endoscope includes a hollow needle of about 18-gauge, a lens system within the needle, an image transmitting bundle of flexible fiber-optic rods within the needle, a plurality of illumination transmitting fiber-optic rods within the needle, an operative channel within the needle, and apparatus to shift the image transmitting bundle with respect to the lens system and needle to provide focus adjustment for focusing the endoscope on objects at various distances from the end of the needle. (See Olinger Patent, Abstract).

The Webb Publication relates to a scanning confocal microscopy system, especially useful for endoscopy with a flexible probe which is connected to the end of an optical fiber (9). The probe has a grating (12) and a lens (14) which delivers a beam of multi-spectral light having spectral components which extend in one dimension across a region of an object and which is moved to scan in another dimension. The reflected confocal spectrum is measured to provide an image of the region. (See Webb Publication, Abstract).

The Baker Patent relates to angioplasty system and method for identification and laser ablation of atherosclerotic plaque at a target site in a blood vessel. Such system

and method employ fluorescence analysis for identification of noncalcified plaque and calcium photoemission analysis for identification of calcified plaque. Calcified plaque is identified by time domain analysis of calcium photoemission. A high energy pulsed ultraviolet laser can be used for stimulation of fluorescence and for stimulation of calcium photoemission. The system is capable of distinguishing between calcium photoemission and a defective condition of optical fibers that are used to deliver laser energy to the target site. In an another embodiment of the angioplasty system, calcium photoemission is identified during a nonablative initial portion of the laser ablation pulse. When calcium photoemission is not identified, the laser ablation pulse is terminated during the initial nonablative portion thereof. (See Baker Patent, Abstract).

Applicants' invention, as recited in amended independent claim 68, relates to an apparatus for obtaining information associated with an anatomical structure which comprises, *inter alia*:

an image-forming lens arrangement which is configured to provide there through electro-magnetic radiation, wherein the electro-magnetic radiation is provided by at least one of a broadband source or a wavelength tuned source;

an optical waveguide configured to transmit and receive the information from the structure on a macroscopic scale;

at least one further arrangement which is structured to obtain the information based on a radiation obtained from the structure, wherein the information is at least one of a two-dimensional image or a three dimensional image; and

a dispersive arrangement configured to receive at least one portion of the electro-magnetic radiation and forward a dispersed radiation thereof to at least one section of the structure regarding which the information is being obtained on a macroscopic scale, wherein the image-forming lens arrangement forms an image of the anatomical structure.

Applicants' invention, as recited in amended independent claim 89, relates to an apparatus for obtaining diagnostic information associated with an anatomical structure and modifying at least one property of at least one portion of the structure which comprises, *inter alia*:

an image-forming lens arrangement

an optical waveguide configured to transmit and receive the information from the structure on a macroscopic scale ..., wherein the electro-magnetic radiation is provided by at least one of a broadband source or a wavelength tuned source;

at least one further arrangement which is structured to obtain the information based on a radiation obtained from the structure, wherein the information is at least one of a two-dimensional image or a three dimensional image; and

a dispersive arrangement configured to receive the first and second electromagnetic radiations, wherein the image-forming lens arrangement forms an image of the anatomical structure.

Applicants' invention, as recited in independent claim 113, relates to an apparatus for obtaining information associated with an anatomical structure which comprises, *inter alia*:

an image-forming lens arrangement configured to provide a plurality of electro-magnetic radiations, and a dispersive arrangement configured to receive the electro-magnetic radiations and forward a dispersed radiation of each of the electro-magnetic radiations to at least one portion of the structure regarding which the information is being obtained and at least partially overlap the at least one portion ..., wherein the image-forming lens arrangement forms an image of the anatomical structure , and wherein the electro-magnetic radiations are provided by at least one of a broadband source or a wavelength tuned source;

an optical waveguide configured to transmit and receive the information from the structure on a macroscopic scale; and

at least one further arrangement which is structured to obtain the information based on a radiation obtained from the structure, wherein the information is at least one of a two-dimensional image or a three dimensional image.

Applicants' invention, as recited in independent claim 125, relates to an apparatus for obtaining information for an anatomical structure which comprises, *inter alia*:

an image-forming lens arrangement configured to provide an electro-magnetic radiation, wherein the electro-magnetic radiation is provided by at least one of a broadband source or a wavelength tuned source,

a dispersive arrangement configured to receive at least one portion of the electro-magnetic radiation and forward a dispersed radiation thereof to a particular location on at least one portion of the structure regarding which the information is being obtained ..., wherein the image-forming lens arrangement forms an image of the anatomical structure;

an optical waveguide configured to transmit and receive the information from the structure on a macroscopic scale; and

at least one further arrangement which is structured to obtain the information based on a radiation obtained from the structure, wherein the information is at least one of a two-dimensional image or a three dimensional image.

Applicants' invention, as recited in independent claim 131, relates to an apparatus for obtaining information associated with an anatomical structure which comprises, *inter alia*:

an image-forming lens arrangement which is configured to provide there through electro-magnetic radiation, wherein the electro-magnetic radiation is provided by at least one of a broadband source or a wavelength tuned source;

an optical waveguide configured to transmit and receive the information from the structure on a macroscopic scale;

at least one further arrangement which is structured to obtain the information based on a radiation obtained from the structure,

wherein the information is at least one of a two-dimensional image or a three dimensional image; and

a dispersive arrangement configured to receive at least one portion of the electro-magnetic radiation and forward a dispersed radiation thereof to at least one portion of the structure regarding which the information is being obtained ..., wherein the image-forming lens arrangement forms an image of the anatomical structure.

Thus, each of independent claims 68, 89, 113, 125 and 131 recites (i) an “image-forming lens arrangement” and a “dispersive arrangement”, (ii) that the radiation is forwarded to at least one portion of a “structure regarding which the information is being obtained”, and (iii) that the image-forming lens arrangement forms an image of the anatomical structure. In addition, each of independent claims 68, 89, 113, 125 and 131 now recites (i) that the electro-magnetic radiation(s) is/are provided by a broadband source and/or a wavelength tuned source (as previously recited in now cancelled claim 69), (ii) an optical waveguide configured to transmit and receive the information from the structure on a macroscopic scale (as previously recited in now cancelled claim 73), and (iii) at least one further arrangement which is structured to obtain the information based on a radiation obtained from the structure, wherein the information is at least one of a two-dimensional image or a three dimensional image (as previously recited in now cancelled claim 73).

First, as previously stated in Applicants’ prior response. it is respectfully asserted that the Kittrell Patent fails to teach, suggest or disclose that **the image-forming lens arrangement forms an image of the anatomical structure**, as recited in amended independent claims 68, 89, 113, 125 and 131. In the Final Office Action, the Examiner again pointed to lenses 40 and 41 as being equivalent to the lens arrangement recited in each of amended independent claims 68, 89, 113, 125 and 131. (See latest Final Office

Action, p 5). However, the portion of the Kittrell Patent that is pointed to by the Examiner as being the lens arrangement that form an image cannot actually form an image at all. For example, the glass 12 may receive radiation, and may curved, but cannot at all form an image of any anatomical structure.

Indeed, as shown in Figs. 21 and 22 of the Kittrell Patent, the lens 41 forwards the radiation to a spectral analyzer 60. Thus, it appears that the Examiner equates this spectral analyzer 60 with the dispersive arrangement, as recited in amended independent claims 68, 89, 113, 125 and 131. Even if the lens 41 of the Kittrell Patent can be equated to the recited lens arrangement of amended independent claims 68, 89, 113, 125 and 131, such lens 41 only forms an image of the fibers, and certainly not of the anatomical structure. Clearly, no image at all (any of spectral, tomographic, etc.) **of the anatomical structure** is formed by the lens 41 of the Kittrell Patent. In addition, the shield 12 of the Kittrell Patent does not form an image of anything, much less the anatomical structure.

For example, the image can be formed on the lens arrangement using an equation know to those having ordinary skill in the art, e.g., $1/f = 1/o + 1/l$, where f is a focal length, o is an object distance to the lens, and l is an distance from the lens to the location where the image is formed. This is the equation that would form any image of the on and by the lens arrangement. Indeed, none of the lenses in the Kittrell Patent are in a configuration which would allow any images to be formed thereon. For example, the Examiner previously alleged that the Kittrell's shield and prism of Fig. 13D can be the combination as recited in independent claims. However, this combination does not allow the shield 12 to satisfy the above equation which is known to be image formation.

Then, in the latest Final Office Action, the Examiner pointed to Fig. 23 of the Kittrell Patent, and contended that the lens 40 provided in such figure being such recited lens arrangement. (See Final Office Action, p. 2, second full para.). However, the lens 40 only receives light from a source and the fiber, but does not form any image (any of spectral, tomographic, etc.) thereon. In Fig. 23, it is clear that the lens 40 of the Kittrell Patent transmits the radiation to the fiber, but that such lens 40 does not form any image.

Thus, it is respectfully asserted that the Kittrell Patent lacks **the image-forming lens arrangement which forms an image of the anatomical structure**, as recited in amended independent claims 68, 89, 113, 125 and 131 of the present application.

Second, as previously stated, while the lens 41 of the Kittrell Patent may be image-forming, the radiation being forwarded to the spectral analyzer 60 is in no way then forwarded to at least one section of any structure, much less regarding which the information is being obtained. In summary, the configuration of *the image-forming lens providing the radiation to the dispersive arrangement which then forwards the dispersed radiation to the structure*, as recited in amended independent claims 68, 89, 113, 125 and 131, is in no way described or shown in the Kittrell Patent, much less in Figs. 21 and 22 thereof.

Third, as previously argued by Applicants, Figs. 13A-13F of the Kittrell Patent show that the transparent shield/enclosure 12 appears to have an equal distance between the inner surface and the outer surface along the section thereof through which the radiation is exhibited. Thus, no image can be formed thereby. In addition, the lens 41 of the Kittrell Patent which forwards the radiation from a laser to the fibers 20 also do not

provide or form any images, and thus cannot be equated to the “**image-forming lens arrangement**”, as recited in amended independent claims 68, 89, 113, 125 and 131.

Fourth, as agreed to by the Examiner during the Interview, the Kittrell Patent fails to teach, suggest or disclose the additional recitations of each of independent claims 68, 89, 113, 125 and 131, as follows:

- that the electro-magnetic radiation(s) is/are provided by a broadband source and/or a wavelength tuned source (as previously recited in now cancelled claim 69),
- an optical waveguide configured to transmit and receive the information from the structure on a macroscopic scale (as previously recited in now cancelled claim 73), and
- at least one further arrangement which is structured to obtain the information based on a radiation obtained from the structure, wherein the information is at least one of a two-dimensional image or a three dimensional image (as previously recited in now cancelled claim 73).

The Olinger Patent, the Webb Publication and/or the Baker Patent do not cure such deficiencies of the Kittrell Patent, and the Examiner does not contend that they do.

Accordingly, Applicants respectfully submit that the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent, does not render obvious the subject matter recited in amended independent claim 68, 89, 113, 125 and 131. The claims which depend from such independent claims are also not taught, suggested or disclosed by the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent for at least the same reasons.

Regarding claim 147, this claim depend from independent claims 74 and independent claim 68, and also recites that “**the optical fiber has an end portion that is**

provided at a position of an image plane of the at least one portion which is established by the lens.” In the latest Final Office Action, the Examiner contends that such subject matter is disclosed in the Kittrell Patent by stating that the device of the Kittrell Patent “both illuminates the anatomical structure via the optical fiber as well as collects return light via the optical fiber. The return light enters the optical fibers after passing through the lens/optical shield structure.” (See latest Final Office Action, p. 4, first full para.).

However, it is again respectfully asserted that the Kittrell Patent nowhere discloses that the optical fiber has **an end portion that is provided at a position of an image plane of at least one portion** of the anatomical structure which is established by the lens. Indeed, the alleged combination of the Kittrell Patent with any of the Olinger Patent, the Webb Publication and/or the Baker Patent fails to teach or suggest the subject matter recited in this claim, at least for the reasons presented herein and in the prior response filed by Applicants on May 7, 2010. In addition, since the lens/shield of the Kittrell Patent does not form an image as discussed herein above, the end portion of Kittrell’s fiber is not provided at any position of the image plane of the portion(s).

Accordingly, Applicants respectfully request the Examiner to confirm that the subject matter of claim 147 is not taught, suggested or disclosed by the Kittrell Patent, taken alone or in combination with the Olinger Patent, the Webb Publication and/or the Baker Patent.

Thus, for at least these reasons, withdrawal of the final rejections of these claims under 35 U.S.C. §§ 102(b) and 103(a) is respectfully requested.


V. ALLOWABLE SUBJECT MATTER

Applicants gratefully acknowledge the Examiner's indication that claims 142-145 are allowed.

VI. CONCLUSION

In light of the foregoing, Applicants respectfully submit that all pending claims 68-82, 84-102, 104-148 and 150-162 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,



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